

**REMARKS/ARGUMENTS**

Claims 1-3, 7, 34-43, 106, 107, and 112 have been examined. Applicants note with appreciation the allowance of claims 77-86. Claims 79-82 have been amended. Claims 113-126 have been added. Claims 1-76 and 87-105 have been canceled. Re-examination and reconsideration of remaining claims 106-126 are respectfully requested.

As an initial matter, Applicants request that the Examiner send confirmation of the consideration of the references cited in the Information Disclosure Statement filed by Applicants on April 8, 2004.

**Restriction Requirement**

Applicants have canceled claims 4-6, 8-33, 44, 45, 53-76, and 87-105 without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed divisional application.

**Amendments to Specification/Drawings/Claims**

Applicants have amended the specification so that the first paragraph under the heading "Cross-References to Related Applications" now correctly references the entire priority chain associated with U.S. Patent Application No. 10/002,595 pursuant to the requirements under 37 C.F.R. § 1.78 and the Petition to accept an unintentionally delayed domestic priority claim for the benefit of prior filed applications, submitted concurrently herewith. Further, the incorporation by reference to such prior filed applications is supported by the originally filed specification. In particular, page 1, lines 6-9 of the present application, incorporates by reference the full disclosure of U.S. Patent Application No. 10/002,595. The originally filed disclosure of U.S. Patent Application No. 10/002,595 in turn incorporates by reference the full disclosures of the remaining applications on page 1, lines 4-11. As such, no new matter has been added.

The specification and drawings have further been amended to correct inadvertent typographical errors. In particular, the units of "ug", "ug/day", "ug/mg", "um", "umol", "umol/L" have been corrected to "μg", "μg/day", "μg/mg", "μm", "μmol", "μmol/L" so as to reflect the correct measurement unit denoted by micro symbol. This amendment is supported by the

originally filed specification, and in particular in paragraph numbers 48, 88,124, 167, 195, 205 and 206. As such, no new matter has been added thereby.

The specification and claims 79-82 have been amended to correct further inadvertent typographical errors. In particular, the flux density measurement of "ug/(cm<sup>2</sup>s)" has been corrected to "g/(cm<sup>2</sup>s)" so as to reflect the correct measurement unit of grams. It is quite clear to one of ordinary skill in the art that the individual dimensions of the units should belong to the same system of measurement, in this case the centimeter-gram-second (CGS) system. Further, the CGS system is often used to denote flux density measurements. As such, one of ordinary skill in the art would know that the flux density of the therapeutic capable agent across the rate-controlling element to the targeted tissue site would be expressed in grams-centimeter-second and that this one million fold difference in units is a clear mistake. Hence, no new matter has been added thereby.

#### Claim Objections/Rejections

Claims 46-52 have been objected to under 37 C.F.R. § 1.75(c). Claims 1-3, 34-43, 106, 107, and 112 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 25-29, and 33 of U.S. Patent No. 6,471,980. Claims 1-3, 7, and 34-43 have been rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by U.S. Patent No. 6,663,662 issued to Pacetti et al. In order to expedite prosecution of the present case, Applicants have canceled claims 34-43 and 46-52 without prejudice. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed continuation application. With respect to remaining claims 106, 107, and 112, a terminal disclaimer is being filed herewith to obviate this non-statutory double patenting rejection. Dependent claims 108-111 stand withdrawn as being drawn to a non-elected species. Currently, independent claim 106 is generic with respect to these claims. As such, Applicants request allowance of independent claim 106 (and dependent claims 107-112).

Appl. No. 10/017,500  
Amtd. dated July 16, 2004  
Reply to Office Action of March 29, 2004

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Added Claims

New dependent claims 113-126 have been added. Support for these new claims can be found throughout the originally filed specification, and in particular with reference to paragraph number 140 for claims 113-118 and paragraph number 88 for claims 119-126. Claims 113-120 depend upon allowed claim 77, claims 121 and 122 depend upon allowed 79, claims 123 and 124 depend upon allowed claims 83, and claims 125 and 126 depend upon allowable independent claim 106. As such, Applicants respectfully request allowance of new claims 113-126.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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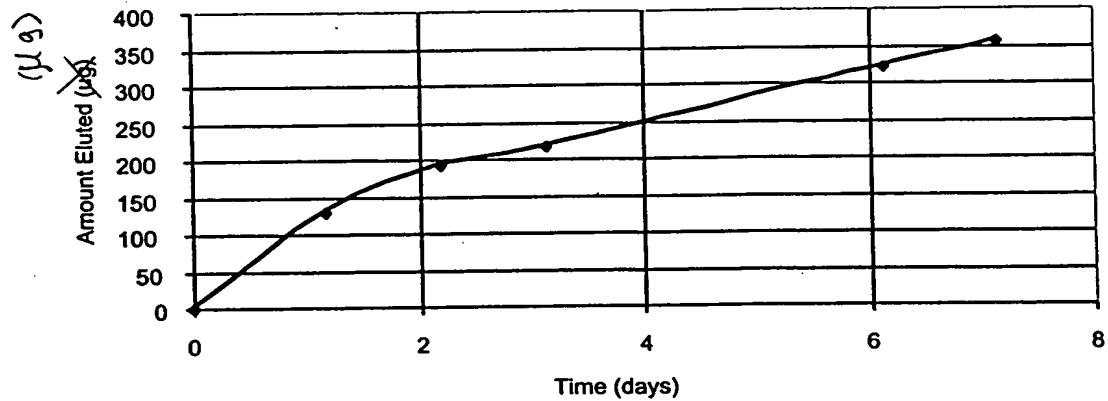


FIG. 17A

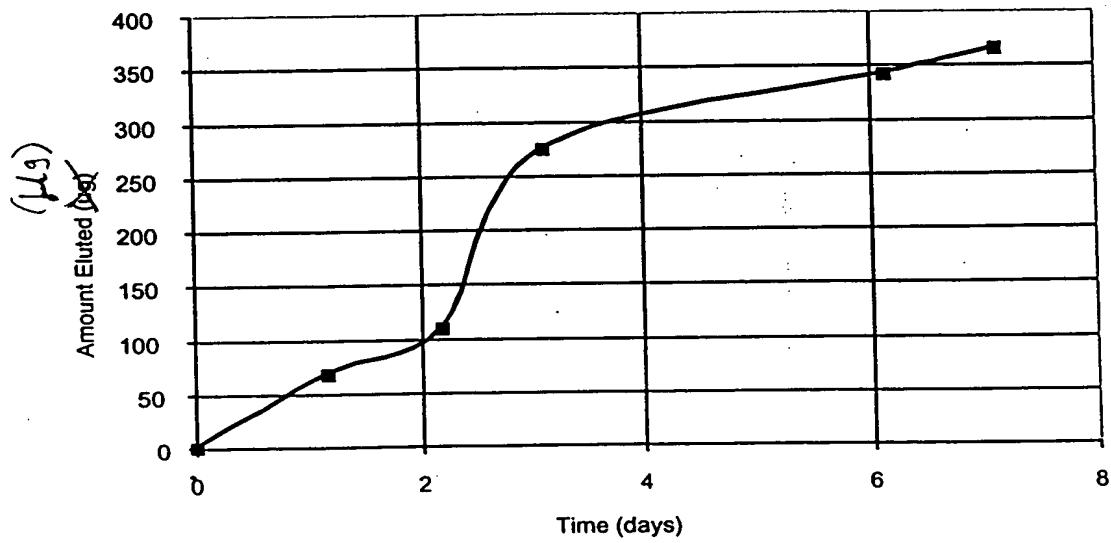


FIG. 17B

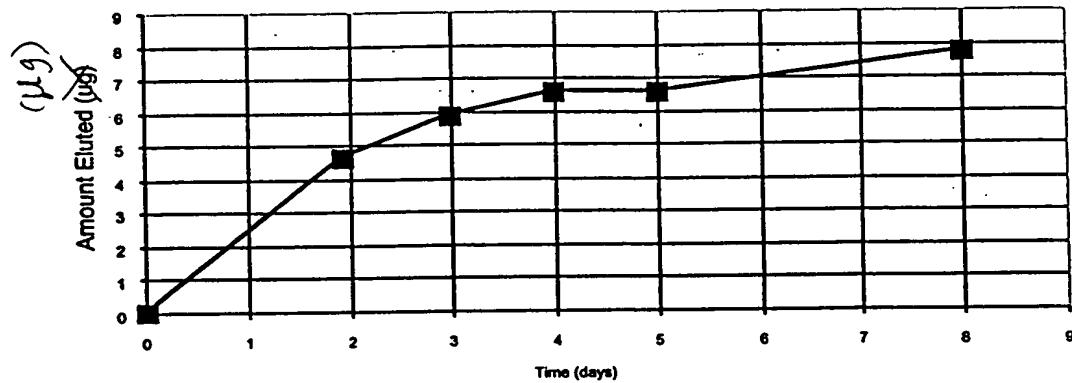


FIG. 18A

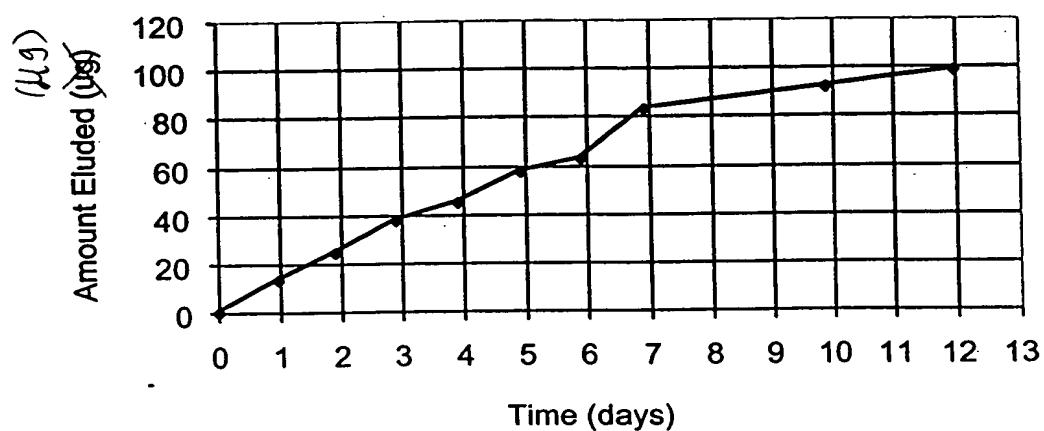


FIG. 18B

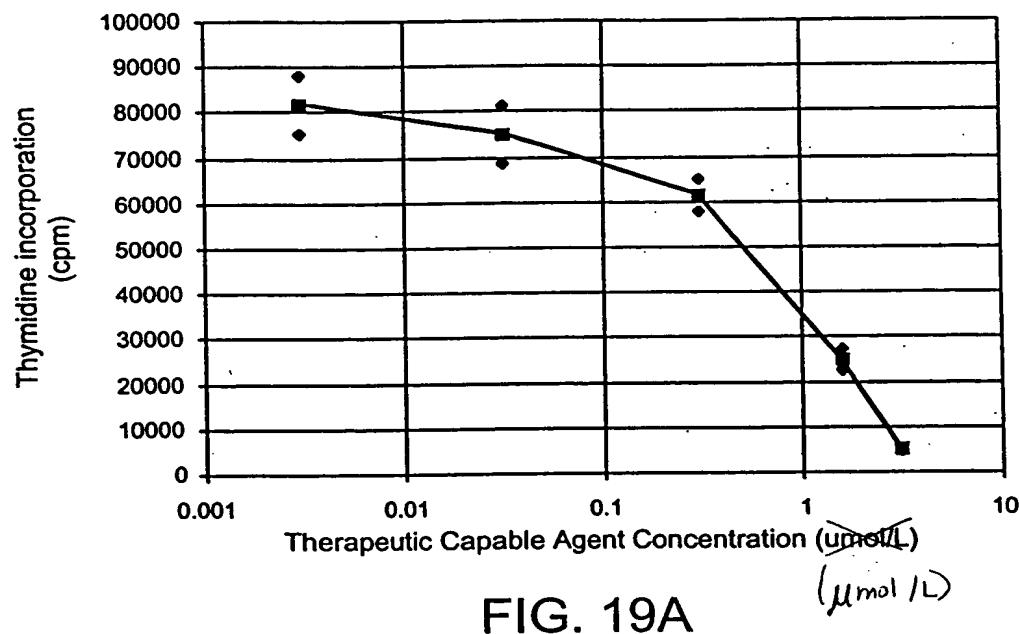


FIG. 19A

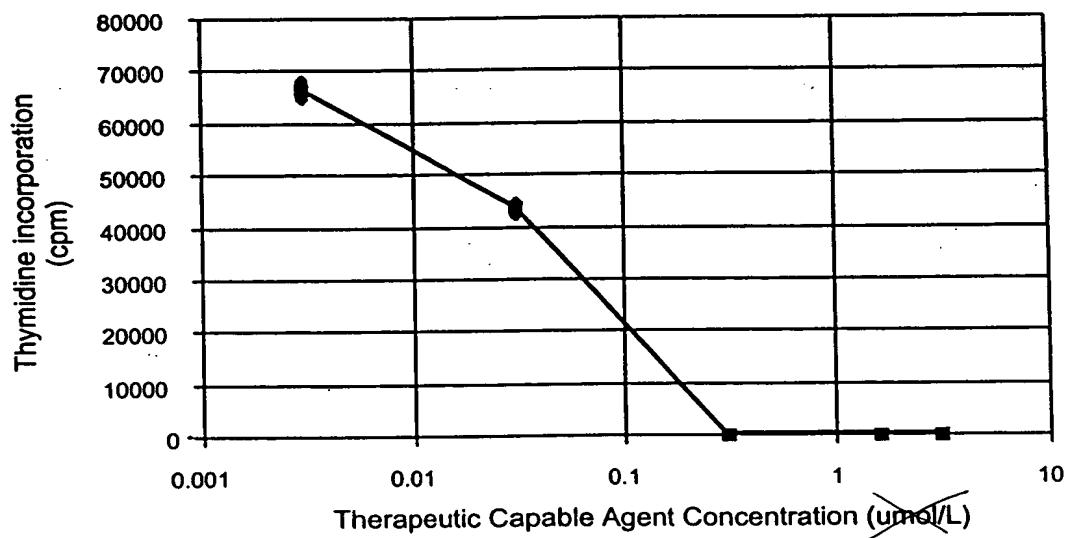


FIG. 19B

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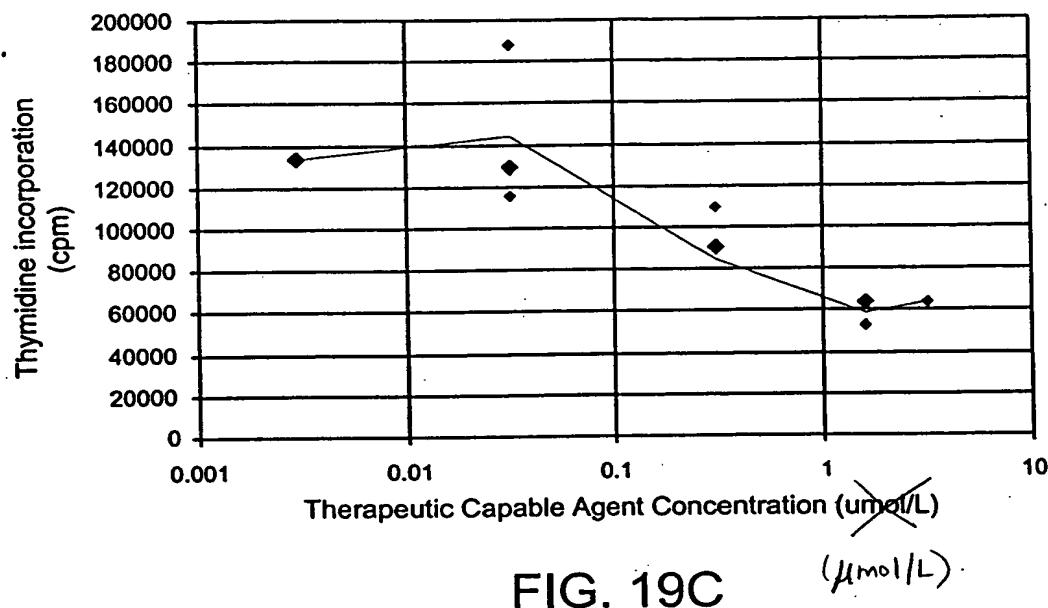


FIG. 19C

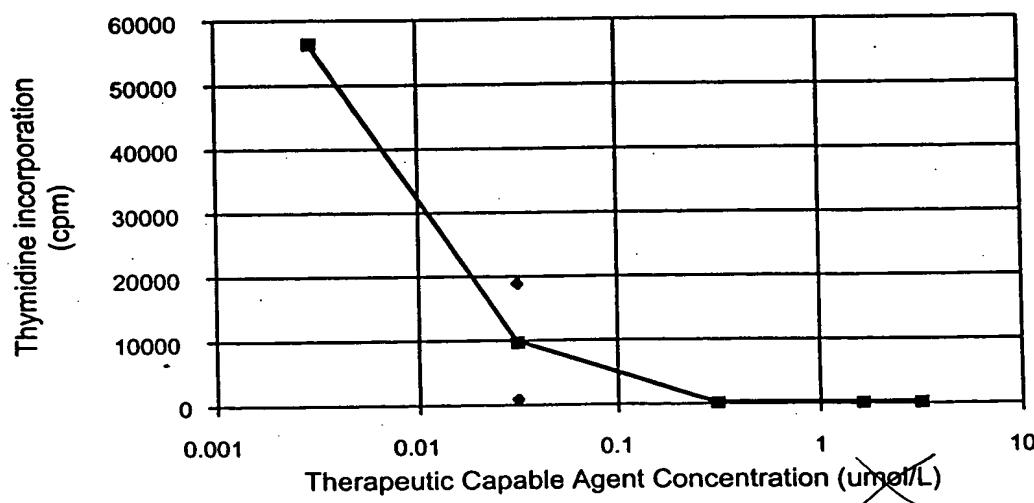


FIG. 19D

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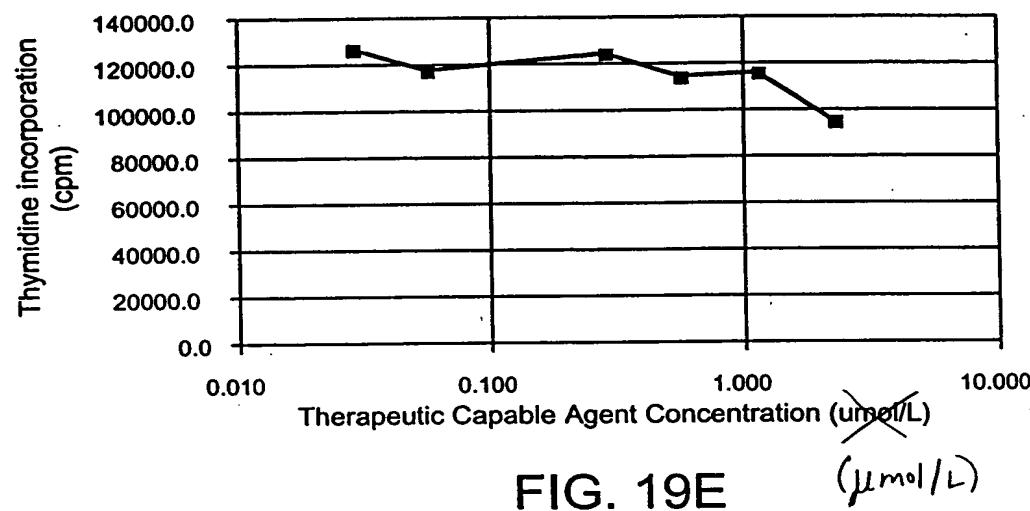


FIG. 19E      ( $\mu\text{mol/L}$ )

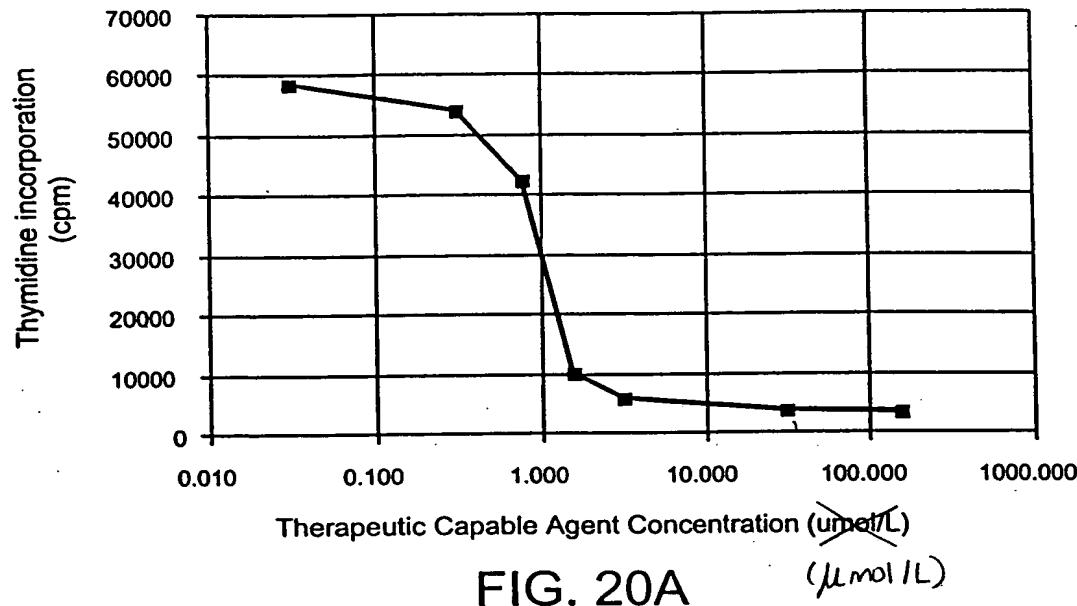


FIG. 20A

( $\mu\text{mol/L}$ )

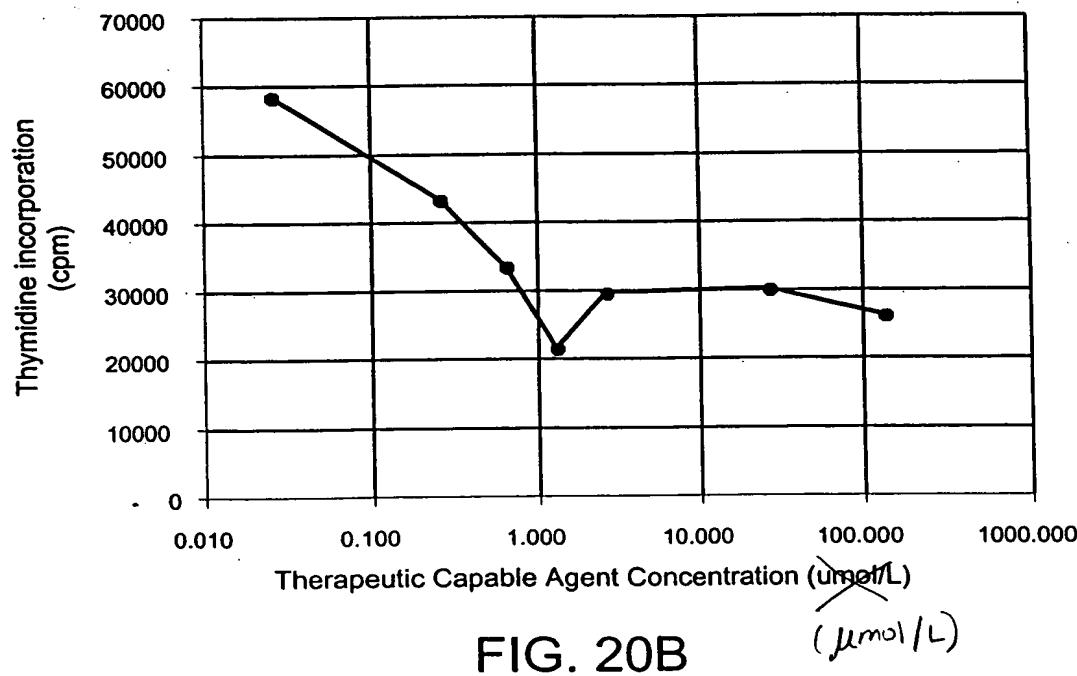


FIG. 20B

( $\mu\text{mol/L}$ )

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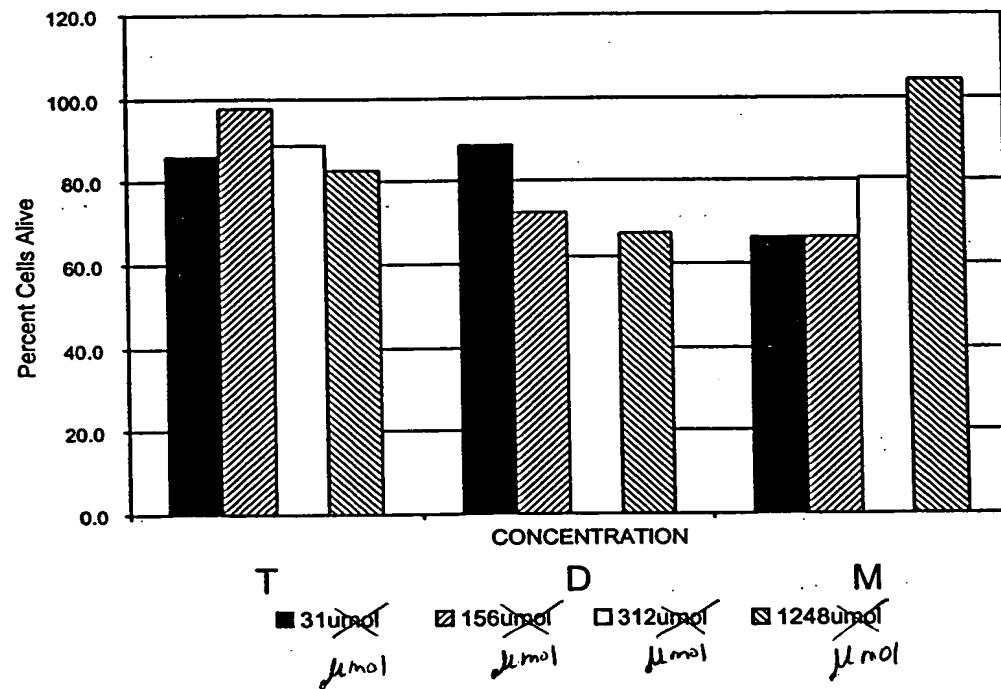
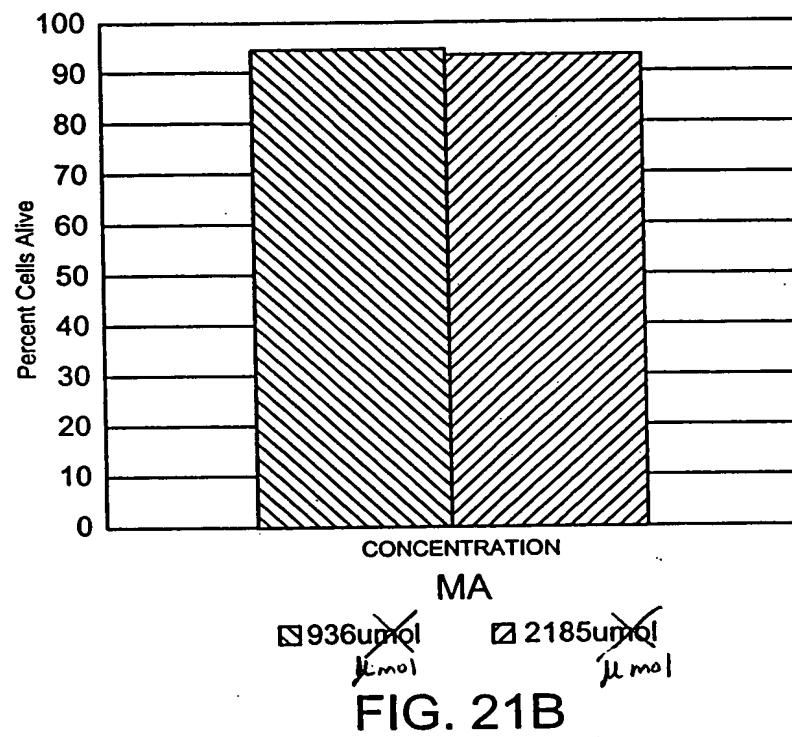


FIG. 21A



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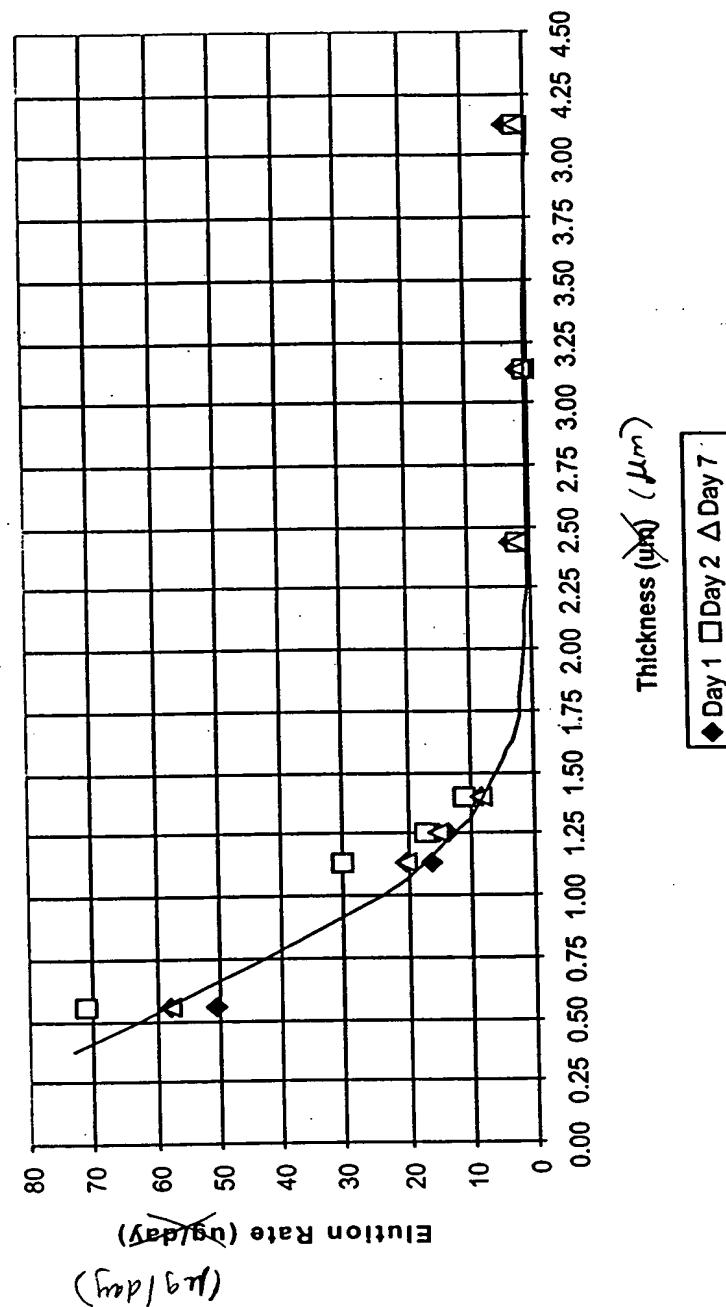


FIG. 22

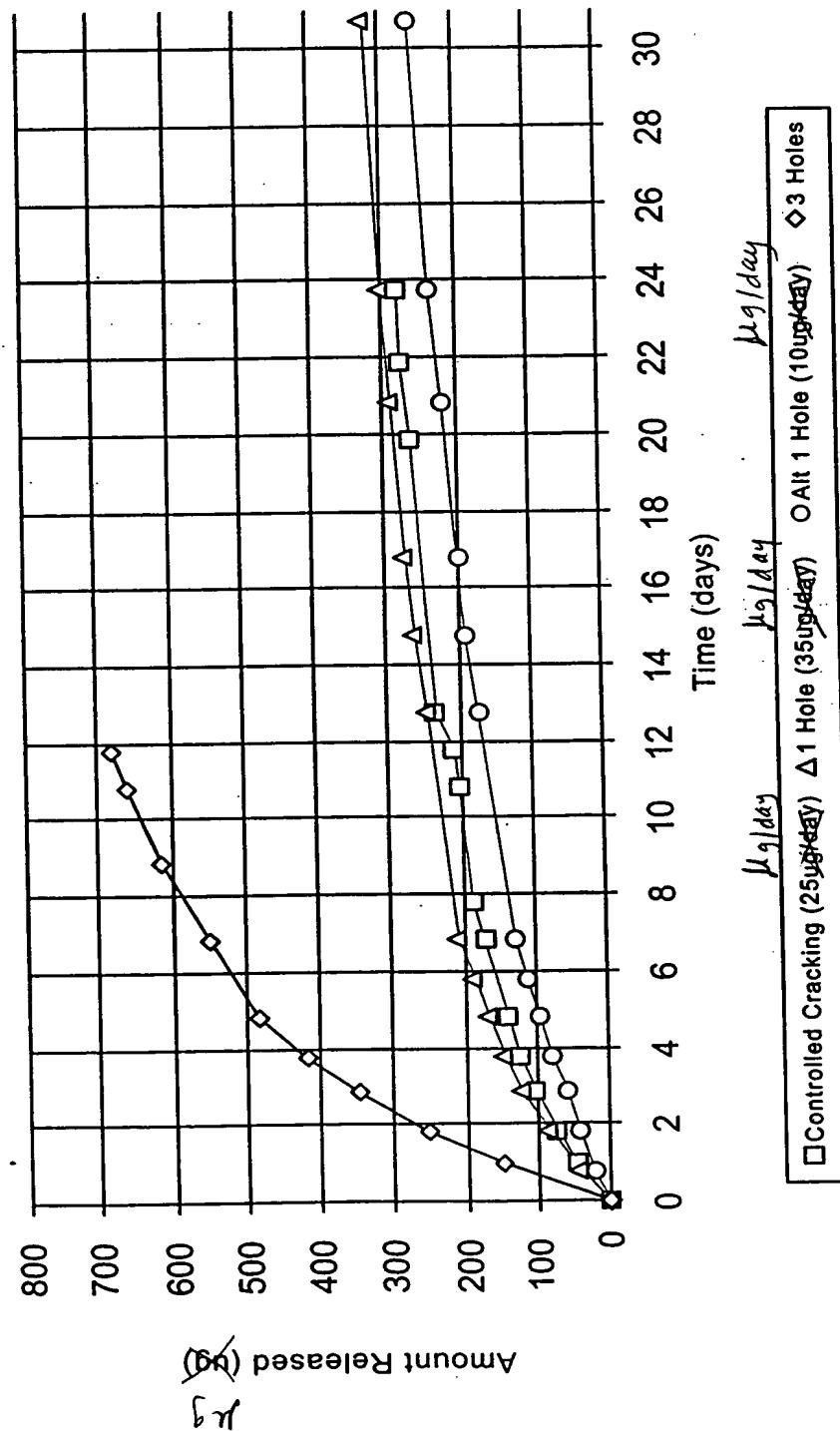


FIG. 23A

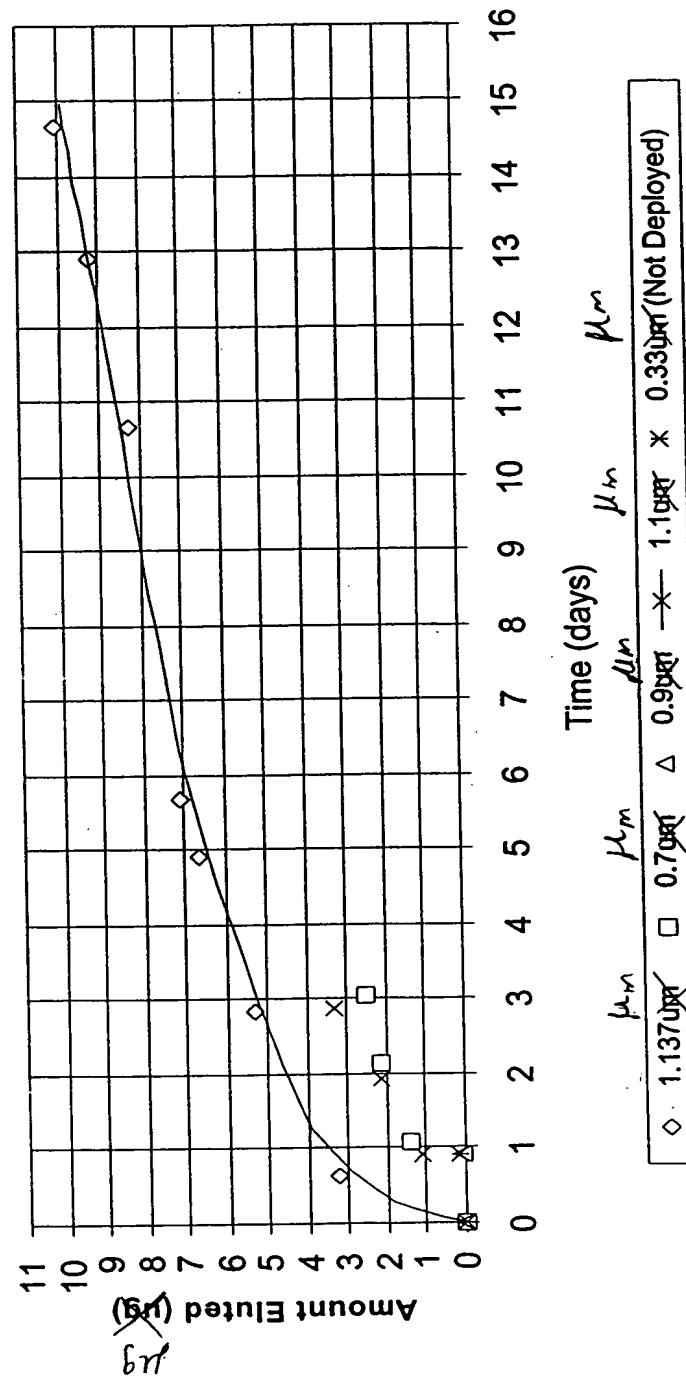


FIG. 23B

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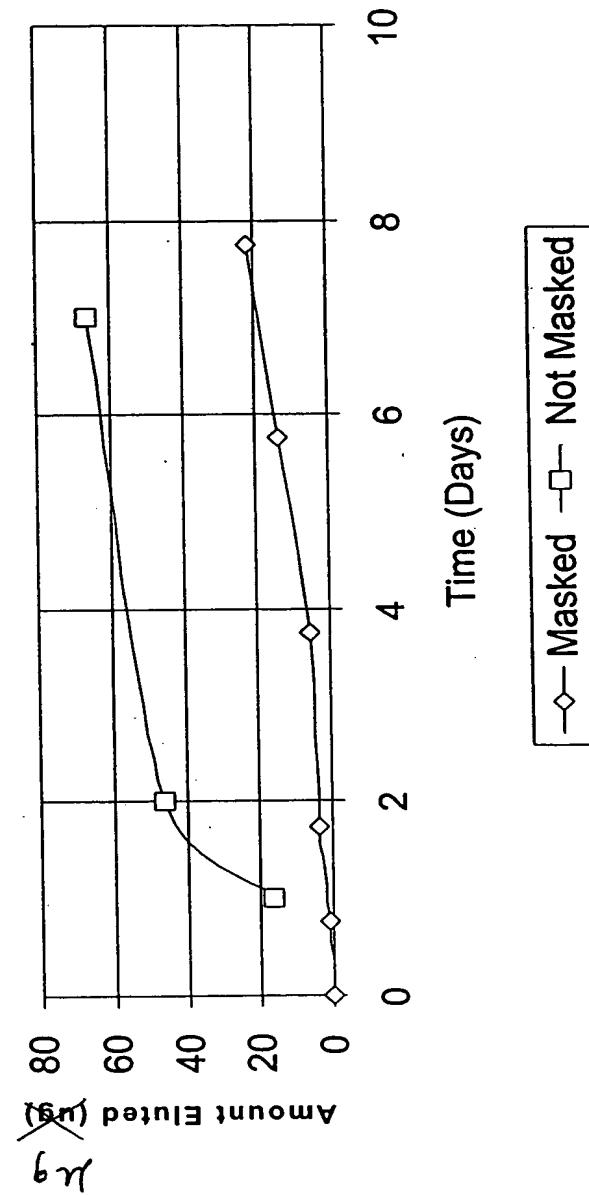


FIG. 24

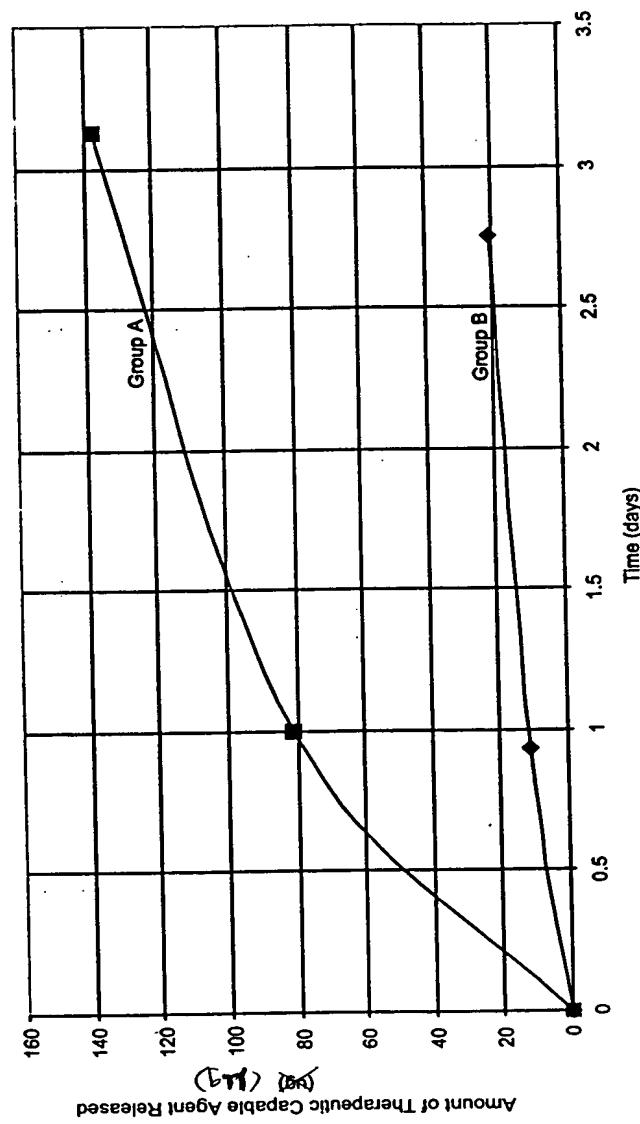


FIG. 25